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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,020	10/12/2001	Alan J. Magill	P66822US0 (WRAIR 98-40/46	7596

7590 08/05/2004

Office of the Staff Judge Advocate
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-JA (Ms. Elizabeth Arwine)
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER	
SHAHNAN SHAH, KHATOL S	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/975,020	MAGILL ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *24 June 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *4, 11, 12, 22-25 and 29-31*.

   Claim(s) withdrawn from consideration: None

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Attachment to Advisory Action

1. Applicants' response to a final action, under 37 CFR 1.116, received 6/24/2004 is acknowledged. The response has been entered.

2. Currently claims 4, 11, 12, 22-25 and 29-31 are pending and under consideration.

3. Applicants' notice of appeal, received 6/24/2004 is acknowledged.

4. Applicants' declaration under 37 CFR 1.132, received 6/24/2004, is acknowledged. The affidavit of the Dr. Jonathan B. Berman has not been timely filed see MPEP 761.01. However, the examiner has considered the affidavit in order to expedite prosecution.

Rejections Maintained

5. Rejection of claims 4, 11, 12, 22-25, 29 and 30 under 35 U.S.C. 102(b), made in paragraph 10 of the office action mailed 8/26/2003 is maintained.

The rejection was as stated below:

Claims 4, 11, 12, 22-25 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Leishmania Research project DoD-8B (copy attached) or Stitler et al. (Production of Leishmania Skin Antigen Test GMP Protocol requirements 1 and 2, 1994 and 1995). Claims are drawn to a microfluidized lysate preparation from a least one Leishmania parasite.

Leishmania Research project DoD-8B and Stitler et al teach a microfluidized lysate preparation from Leishmania parasite manufactured in May 1995 (see attached papers specially abstract #300, page 186, 44th Annual Meeting of American Society of Tropical Medicine and Hygiene). The prior art teaches the claimed product. Limitations such as use of the product in

kits or pharmaceutical composition will be inherent in the teachings of Leishmania Research project DoD-8B.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants' arguments filed 6/24/04 have been fully considered but they are not persuasive.

Applicants argue that all the cited prior art disclose is that first generation lysate preparations were reformulated in order to prevent hypersensitivity to preparation and that the reformulated preparations were the subject of IND submitted to FDA. Applicants further argue, that the cited prior art do not teach absence of dextran specifically in the reformulated preparation. Applicants further argue that there are several ways to microfluidize a preparation, including freeze thawing and sonification methods known in the art. The present invention as claimed requires that a slurry of at least one Leishmania parasite strain is microfluidized with a sudden release of pressure.

It is the examiner's position that the claims are drawn to a product by a process. The prior art teaches the claimed product (i.e. Microfluidized lysate from at least one Leishmania parasite). How this product is prepared does not impart any patentability weight on the claimed product. Even applicants in their arguments admitted that there are several ways to microfluidize a

preparation, including freeze thawing and sonification methods. Sonification method can also be considered as a method of disrupting the parasite strain with a sudden release of pressure (i.e. mechanical cavitation) through production of extreme sound.

The cited prior art teaches the invention as claimed by the applicant. The cited prior art (Project DoD-8B) teaches and has completed both phase I and II of the of development of LSTA. In 1999 the second generation of the lysate was reformulated into a liquid product. There is no recitation that in the cited prior art that the lysate of prior art contains dextran barring evidence to the contrary.

Applicants have also cited an affidavit under 37 CFR 1.132 by Dr. Jonathan B. Berman to over come the rejection. The affidavit is insufficient to overcome the rejection of claims 4, 11, 12, 22-25 and 29-31 based upon 102 (b) as being anticipated by cited prior art as set forth in the last Office action because:

The examiner has reviewed Dr. Berman's declaration carefully. The examiner agrees with Dr. Berman in regard to the finding that Leishmania Research project DoD-8B does not recite that the Microfluidized –lysate preparation is free of dextran. But the prior art does not recite that the Microfluidized –lysate would contain dextran either. Dr. Berman has not submitted evidence in form of laboratory or analytical data that the preparation was tested for the presence of dextran. Therefore, the examiner concludes that the preparation is free of dextran barring evidence to the contrary.

Conclusion

6. No claims are allowed. Claims 1-3 stand rejected. Claim 4 is objected to as being depended from rejected claim 1.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

August 2, 2004

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER